



DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 381

[Docket No. FSIS 2021-0004]

RIN 0583-AD84

**Condemnation of Poultry Carcasses Affected with Any Form of
Avian Leukosis Complex; Recission**

AGENCY: Food Safety and Inspection Service (FSIS), U.S.

Department of Agriculture (USDA).

ACTION: Final rule.

SUMMARY: FSIS is amending the poultry products inspection regulations to rescind several regulations related to the inspection and condemnation of poultry carcasses affected with any of the forms of avian leukosis complex.

DATES: Effective [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Rachel Edelstein, Assistant Administrator, Office of Policy and Program Development; Telephone: (202) 937-4272.

SUPPLEMENTARY INFORMATION:

Background

Avian Leukosis Complex (also referred to as avian leukosis) is a rare condition in poultry that includes three virally-induced, tumor-causing diseases in poultry, none of which are

transmissible to humans.¹ The three characterized diseases are Marek's Disease caused by Marek's Disease virus (MDV), Lymphoid Leukosis, and Reticuloendotheliosis.²

On March 14, 2022, FSIS proposed to amend the poultry products inspection regulations to rescind several regulations related to the inspection and condemnation of poultry carcasses affected with any of the forms of avian leukosis (87 FR 14182). FSIS proposed these changes in response to a petition from the National Chicken Council (NCC), which requested that the Agency amend its regulations to designate avian leukosis as a trimmable condition rather than a condition that requires condemnation of the entire carcass.³ The petition also requested that FSIS rescind the regulations at 9 CFR 381.36(f)(3) that require young chicken establishments operating under the New Poultry Inspection System (NPIS) to provide a location at a point along the production line to permit an FSIS inspector to inspect for leukosis the first 300 carcasses of each flock, together with their corresponding viscera. In addition, the petition requested that FSIS rescind the regulations at 9 CFR 381.76(b)(6)(iv) that prescribe the 300-bird leukosis inspection procedure under the NPIS. The petition asserted that the current regulations related to leukosis are based on an outdated understanding of this

¹ Schat, K A. and Erb, H.N. Lack of evidence that avian oncogenic viruses are infectious for humans: A review. Avian Diseases, 2014; 58: 345-358.

²Schat, K A. and Erb, H.N. Lack of evidence that avian oncogenic viruses are infectious for humans: A review. Avian Diseases, 2014; 58: 345-358.

³ The petition and FSIS' response are available at: Petition to Treat Avian Leukosis as a Trimmable Condition | Food Safety and Inspection Service (usda.gov).

poultry disease, impose unnecessary costs on industry, and present a potential barrier to young chicken establishments that may want to convert to NPIS.

As FSIS explained in the proposed rule, the Agency evaluated the available scientific information on avian leukosis and concluded that there was scientific support for treating avian leukosis as a trimmable condition under 9 CFR 381.87 in all poultry establishments operating under FSIS' mandatory and voluntary inspection.

Final Rule

After carefully considering comments submitted on the proposed rule, FSIS is finalizing the proposal with no changes. Therefore, FSIS is rescinding the regulation (9 CFR 381.82) that requires condemnation of all poultry carcasses affected with any of the forms of avian leukosis. FSIS is also rescinding the regulation (9 CFR 381.36(f)(3)) that requires young chicken slaughter establishments operating under NPIS to provide a location along the production line at which a FSIS inspector inspects the first 300 carcasses of each flock together with associated viscera for leukosis, as well as the regulation that prescribes inspection procedures for avian leukosis in young chicken slaughter establishments operating under NPIS (9 CFR 381.76(b)(6)(iv)). Under this final rule, carcasses affected with avian leukosis will be subject to the amended 9 CFR 381.87, which provides that any organ or other carcass part affected with tumors may be trimmed and that the unaffected parts of the

carcass may be inspected and passed. The amended 9 CFR 381.87 also requires condemnation of any organ or other part of a carcass that is affected by a tumor where there is evidence of metastasis or that the general condition of the bird has been affected by the size, position, or nature of the tumor.

Summary of Comments and Responses

FSIS received 15 comments on the proposed rule from 1 organization representing the poultry industry, 2 consumer groups, and 12 individuals. Most of the commenters supported the proposed rule. One individual and two consumer groups opposed the proposed rule. A summary of comments and FSIS responses follows.

Public Health

Comment: Two consumer groups stated that poultry with avian leukosis should be condemned for unwholesomeness under 21 U.S.C 453(g)(3). Also, two individuals were concerned that because avian leukosis nodules or tumors may be extremely small, poultry products affected by avian leukosis may not be free from unwholesome defects, even if they are trimmed.

Response: As FSIS explained in the proposed rule, avian leukosis is a rare condition. Less than 0.01 percent of total young chickens slaughtered, are condemned every year for avian leukosis, based on Agency data from 2015 to 2019 (87 FR 14182, 14184). Given the low incidence rate and the fact that FSIS inspectors are trained to inspect for avian leukosis, it is unlikely for unwholesome product to be inspected and passed.

FSIS will continue to condemn carcasses and parts when there is evidence of metastasis or that the general condition of the bird has been affected by the size, position, or nature of the tumor (9 CFR 381.87).

Comment: Several individuals stated that under this rule the avian leukosis viruses could mutate and cross species barriers and contaminate humans.

Response: As FSIS explained in the proposed rule (87 FR 14182, 14183), while several studies confirmed the presence of antibodies to MDV, Avian Lymphoid Leukosis, and Reticuloendotheliosis viruses in people working in poultry slaughter and processing establishments, there have been no indications that these poultry diseases are involved in human disease. FSIS also explained that experimental laboratory studies have been unable to establish that any of the avian oncogenic viruses have the ability to infect and replicate in mammalian cells, including humans (87 FR 14182, 14183-84). Therefore, current science does not support that avian leukosis is a human health concern.

Comment: A consumer group argued that two studies^{4,5} showed that chickens suffering from avian leukosis are more likely to

⁴ N.A. Cox, J.L. Wilson, M.T. Musgrove, R.J. Buhr, J.E. Sandler, B.P. Hudson, "Positive Relationship of the Avian Leukosis-J Strain Virus to the Detection of *Campylobacter* in the Digestive Tract and Semen of Broiler Breeder Roosters," *Journal of Applied Poultry Research*, Vol. 13, Issue 1, 2004, Pages 44-47, ISSN 1056-6171, <https://doi.org/10.1093/japr/13.1.44>. (<https://www.sciencedirect.com/science/article/pii/S1056617119314096>)

⁵ Huang JQ, JK Xin, C Mao, F Zhong and JQ Chai, 2013. "Co-infection of avian leukosis virus and *Salmonella pullorum* with the preliminary eradication in breeders of Chinese local 'Shouguang' chickens." *Pak Vet J*, 33(4): 428-432.

carry high loads of foodborne pathogens, such as *Salmonella* and *Campylobacter*.

Response: As FSIS explained in the foregoing and in the proposed rule, less than 0.01 percent of total young chickens slaughtered are condemned every year for avian leukosis, based on Agency data from 2015 to 2019 (87 FR 14182, 14184). Therefore, it would be a rare occurrence for establishments to slaughter and process chickens suffering from avian leukosis. Additionally, FSIS' current regulations address contamination from enteric pathogens. FSIS requires all establishments that slaughter poultry to develop, implement, and maintain written procedures to prevent contamination of carcasses and parts by enteric pathogens, such as *Salmonella* and *Campylobacter* -- regardless of the levels of *Salmonella* and *Campylobacter* -- and fecal material throughout the entire slaughter and dressing operation (9 CFR 381.65(g)). Establishments must incorporate their procedures into their Hazard Analysis and Critical Control Point (HACCP) systems, i.e., HACCP plan, Sanitation Standard Operating Procedure, or prerequisite program. To help poultry slaughter and processing establishments in controlling hazards and meeting the FSIS pathogen performance standards,⁶ FSIS has issued guidelines on best practices for addressing *Salmonella* and *Campylobacter* in poultry products. The guidelines are available at: FSIS Guideline for Controlling Salmonella in Raw

⁶As part of its Salmonella Verification Program, FSIS assesses whether establishments meet pathogen reduction performance standards for *Salmonella* in young chicken and turkey carcasses, raw chicken parts, and not ready-to-eat comminuted chicken and turkey products (see 81 FR 7285).

Poultry: FSIS-GD-2021-0005 and FSIS Guideline for Controlling Campylobacter in Raw Poultry: FSIS-GD-2021-0006.

Comment: A consumer group stated that FSIS should remove avian leukosis inspection requirements only if poultry processors provide supplier data demonstrating a decrease in avian leukosis transmission risk in birds sent to slaughter establishments. The same consumer group and an individual commented that FSIS failed to consider how the proposed rule may lead poultry growers and breeders to reduce precautions against avian leukosis. The consumer group and individual stated that the proposed rule would reduce the economic incentive for growers to vaccinate birds against avian leukosis.

Response: Poultry growers and breeders are not likely to reduce their precautions against avian leukosis because FSIS inspectors will continue to inspect for the condition. FSIS also disagrees that rescinding 9 CFR 381.82 would result in removing the economic incentive to vaccinate flocks. Unvaccinated flocks are at risk of resulting in carcasses that are severely affected by lesions or tumors. To avoid trimming and processing costs, slaughter establishments will continue to source birds with minimal to no lesions or tumors. Further, any organ or other part of a carcass affected by a tumor where there is evidence of metastasis or that the general condition of the bird has been affected by the size, position, or nature of the tumor will be condemned under 9 CFR 381.87. Thus, the economic incentive to vaccinate flocks and to breed leukosis-resistant birds remains.

Trimming Lesions

Comment: An individual asked if FSIS inspectors will reduce an establishment's evisceration line speed if they observe tumors on carcasses after the establishment has conducted any trimming or other preparation on the carcass.

Response: Inspectors-In-Charge (IICs) assess whether inspectors can adequately inspect each carcass at the line speed the establishment operates. 9 CFR 381.76, 381.67, and 381.69 contain the regulations for proper presentation for each type of slaughter system and for line speeds based on the health of each flock and the manner in which birds are being presented to the inspector. IICs have the authority to stop or slow line speeds to ensure that establishments maintain process control and online inspection personnel can perform post-mortem inspection of each poultry carcass. Line speed reductions may be necessary when online inspection personnel require additional time to perform post-mortem inspection including if a flock has a high number of carcasses with disease or other conditions. Any inspection personnel may stop the line when necessary to ensure that avian leukosis is trimmed and that a safe and unadulterated product is produced.

Costs

Comment: An individual commented that the savings associated with the proposed rule were not sufficient to justify treating avian leukosis lesions as a trimmable condition.

Response: The Agency disagrees. These regulatory changes are estimated to be net beneficial, will reduce production costs, and will have no impact on public health. However, FSIS is not changing the regulations solely because of the economic benefits. As explained above, FSIS is changing the regulations because of scientific support for treating avian leukosis as a trimmable condition.

Comment: An individual commented that the economic analysis does not include all potential cost savings. According to the commenter, the proposed changes could prevent establishments from having to condemn entire batches of parts if the parts were comingled with parts from a single condemned carcass.

Response: FSIS is aware the proposed rule may benefit industry in multiple ways. However, due to data limitations, the cost benefit analysis only monetized the cost savings associated with the condemned carcasses.

Comment: A consumer group stated that there are methods to test for avian leukosis and keep it out of the food supply chain, but industry does not implement these testing methods for economic reasons.

Response: The proposed rule does not change the economics associated with the growers' decision to use these tests. Infected, unvaccinated birds may still become affected with lesions or tumors and condemned under 9 CFR 381.87 or product from these birds could be trimmed. The condemnation of the entire carcass will still incentivize growers to continue with

the common commercial practice to vaccinate each chicken flock for Marek's Disease and to breed leukosis-resistant birds. Furthermore, establishments would still be motivated to purchase vaccinated birds to avoid potential labor costs and loss of efficiency associated with trimming affected carcasses.

Establishments Producing Fowl

Comment: One individual asked how FSIS intends to handle treating avian leukosis as a trimmable condition in any mature fowl establishments operating under NPIS.

Response: These establishments will be treated the same as young chicken establishments operating under NPIS.

Inspection Resources

Comment: A consumer group noted that under NPIS, establishment employees are responsible for removing tumors. The commenter argued that the Agency has made no determination that identifying the tumors is feasible at allowed line speeds.

Response: Under this final rule, avian leukosis will be treated as other trimmable defects. FSIS has determined that establishments are able to effectively maintain process control while removing trimmable defects at 175 bpm in HACCP Inspection Models Project (HIMP) establishments (see 79 FR 49565, 49572).⁷ Establishments will need to adjust line speeds to ensure they maintain process control and their employees have enough time to trim defects from affected carcasses. If FSIS inspection program personnel find that establishment employees are not properly

⁷Evaluation of HACCP Inspection Models Project (HIMP) (usda.gov)

maintaining process control and trimming defects then, as explained above, FSIS inspection personnel have the authority to stop or slow the evisceration line.

Executive Orders 12866 and 13563, and the Regulatory Flexibility Act

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety benefits, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This final rule has been designated as a "non-significant" regulatory action under section 3(f) of E.O. 12866. Accordingly, the final rule has not been reviewed by the Office of Management and Budget under E.O. 12866.

Economic Impact Analysis

FSIS did not receive any public comments that would require revising the cost benefit analysis. FSIS updated the average weight and price of young chicken to reflect the impact of the final rule in 2021 dollars. This final rule will benefit all poultry slaughter establishments by decreasing the number of carcasses condemned for leukosis. In 2019, young chicken represented 96 percent of total poultry slaughtered and 87 percent of poultry condemned from leukosis. FSIS used young

chicken slaughter totals to estimate the expected benefits for this rule. An average of 62,445 young chicken carcasses, which represents less than 0.01 percent of total young chicken slaughtered,⁸ were condemned every year for leukosis, based on Agency data from 2015 to 2019.⁹ Based on data from the NCC and the USDA Economic Research Service, the 2021 market weight of a young chicken was 6.46 pounds¹⁰ and the 2021 average wholesale price was \$1.01 per pound.¹¹ As such, these chickens would have a wholesale value of roughly \$407,429 in 2021. Allowing establishments to address leukosis by trimming affected areas, rather than condemning the entire carcass, would result in industry cost savings of at least \$407,429 per year.

The final rule will also remove a potential barrier for young chicken establishments that want to convert to the NPIS by eliminating the need to reconfigure lines and make other changes to provide an inspection area for FSIS to conduct the 300-bird leukosis check. Converting to NPIS will benefit these establishments because they would have more flexibility to design and implement production measures tailored to their operations. The final rule will reduce production costs for NPIS

⁸ On average, from 2015 to 2019 about 9 billion young chicken were slaughtered each year.

⁹ FSIS used data from the Public Health Information System (PHIS). PHIS is FSIS's electronic data analytic system, used to collect, consolidate, and analyze data in order to improve public health.

¹⁰ National Chicken Council: Market Weight pounds, live weight: <https://www.nationalchickencouncil.org/statistic/us-broiler-performance/>. Accessed on October 6, 2022.

¹¹ USDA: Economic Research Service: Live Stock Meat: Domestic Data Whole sale price: 2021 Average: Broilers (cents/lb.) National Comp.: <https://www.ers.usda.gov/data-products/livestock-meat-domestic-data/livestock-meat-domestic-data/#Wholesale%20Prices>. Accessed on October 6, 2022.

young chicken establishments by removing the inefficiencies associated with the current 300-bird leukosis checks, such as automatically slowing the line if a leukosis positive flock is identified, even if only a few carcasses demonstrated leukosis-like lesions. Eliminating the 300-bird leukosis checks will also allow FSIS to shift inspection resources currently required for leukosis checks to other offline activities that are more important in ensuring food safety.

This final rule is not expected to result in additional costs to industry, consumers, or FSIS.

Regulatory Flexibility Act Assessment

The FSIS Administrator certifies that, for the purposes of the Regulatory Flexibility Act (5 U.S.C. 601-602), this final rule will not have a significant economic impact on a substantial number of small entities in the United States. The final rule will not increase costs to the industry.

FSIS does not expect this final rule to result in costs to small entities because establishments will not be required to change their procedures unless they choose to address leukosis by trimming affected areas instead of disposing of the entire carcass. Establishments will choose actions that are beneficial to them. In 2021, total poultry industry revenue was estimated at \$76.98 billion.¹² As such, the estimated cost savings of

¹²United States Census Bureau: Annual Survey of Manufactures: Summary Statistics for Industry Groups and Industries in the U.S.: 2021. ECNSVY Annual Survey of Manufactures Annual Survey of Manufactures Area NAICS 311615: Poultry Processing. Accessed on March 6, 2023: <https://data.census.gov/table?q=311615&tid=ASMAREA2017.AM1831BASIC01>.

\$407,429 would be less than 0.01 percent of industry revenue and would not be considered a significant economic impact.

From 2015 to 2019, about 28 percent of the establishments that had poultry carcasses condemned for leukosis were classified as HACCP size small and about 15 percent were HACCP size very small.¹³ Small and very small poultry establishments that choose to address leukosis by trimming affected areas, will benefit from the expected cost savings associated with this final rule.

Paperwork Reduction Act

There are no new paperwork or recordkeeping requirements associated with this final rule under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

E-Government Act

FSIS and USDA are committed to achieving the purposes of the E-Government Act (44 U.S.C. 3601, et seq.) by, among other things, promoting the use of the internet and other information technologies and providing increased opportunities for citizen access to Government information and services, and for other purposes.

Executive Order 12988, Civil Justice Reform

This final rule has been reviewed under E.O. 12988, Civil Justice Reform. Under this rule: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule;

¹³ FSIS used data from PHIS to identify these establishments by HACCP category.

and (3) no administrative proceedings will be required before parties may file suit in court challenging this rule.

Executive Order 13175

This final rule has been reviewed in accordance with the requirements of E.O. 13175, "Consultation and Coordination with Indian Tribal Governments." E.O. 13175 requires Federal agencies to consult and coordinate with tribes on a government-to-government basis on policies that have tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

FSIS has assessed the impact of this rule on Indian tribes and determined that this rule does not, to our knowledge, have tribal implications that require tribal consultation under E.O. 13175. If a Tribe requests consultation, FSIS will work with the Office of Tribal Relations to ensure meaningful consultation is provided where changes, additions and modifications identified herein are not expressly mandated by Congress.

Environmental Impact

Each USDA agency is required to comply with 7 CFR part 1b of the Departmental regulations, which supplements the National Environmental Policy Act regulations published by the Council on Environmental Quality. Under these regulations, actions of

certain USDA agencies and agency units are categorically excluded from the preparation of an Environmental Assessment (EA) or an Environmental Impact Statement (EIS) unless the agency head determines that an action may have a significant environmental effect (7 CFR 1b.4 (b)). FSIS is among the agencies categorically excluded from the preparation of an EA or EIS (7 CFR 1b.4 (b)(6)). FSIS has determined that this final rule, which rescinds 9 CFR 381.82, 381.36(f)(3) and 381.76(b)(6)(iv), and amends 9 CFR 381.87, will not create any extraordinary circumstances that would result in this normally excluded action having a significant individual or cumulative effect on the human environment. Therefore, this action is appropriately subject to the categorical exclusion from the preparation of an environmental assessment or environmental impact statement provided under 7 CFR 1b.4(6) of the U.S. Department of Agriculture regulations.

USDA Non-Discrimination Statement

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To file a program discrimination complaint, a complainant should complete a Form AD-3027, *USDA Program Discrimination Complaint Form*, which can be obtained online at <https://www.usda.gov/forms/electronic-forms>, from any USDA office, by calling (866) 632-9992, or by writing a letter addressed to USDA. The letter must contain the complainant's name, address, telephone number, and a written description of the alleged discriminatory action in sufficient detail to inform the Assistant Secretary for Civil Rights about the nature and date of an alleged civil rights violation. The completed AD-3027 form or letter must be submitted to USDA by:

(1) Mail: U.S. Department of Agriculture
Office of the Assistant Secretary for Civil Rights
1400 Independence Avenue, SW
Washington, D.C. 20250-9410;

(2) Fax: (833) 256-1665 or (202) 690-7442; or

(3) Email: program.intake@usda.gov

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Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS web page located at: <http://www.fsis.usda.gov/federal-register>.

FSIS will also announce and provide a link to it through the FSIS *Constituent Update*, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The *Constituent Update* is available on the FSIS web page. Through the web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an e-mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: <http://www.fsis.usda.gov/subscribe>. Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

List of Subjects in 9 CFR Part 381

Poultry inspection, Poultry and poultry products, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, FSIS is amending 9 CFR part 381 as follows:

Part 381 - - POULTRY PRODUCTS INSPECTIONS REGULATIONS

1. The authority citation for part 381 continues to read as follows:

Authority: 7 U.S.C. 1633, 1901-1906; 21 U.S.C. 451-472; 7 CFR 2.7, 2.18, 2.53.

§ 381.36 [Amended]

2. Amend § 381.36 by removing and reserving paragraph (f) (3).

§ 381.76 [Amended]

3. Amend § 381.76 by removing paragraph (b) (6) (iv).

§ 381.82 [Removed and Reserved]

4. Remove and reserve § 381.82.

5. Revise § 381.87 to read as follows:

§ 381.87 Tumors.

(a) Tumors, including those possibly caused by avian leukosis complex, may be trimmed from any affected organ or other part of a carcass where there is no evidence of metastasis or that the general condition of the bird has been affected by the size, position, or nature of the tumor. Trimmed carcasses otherwise found to be not adulterated shall be passed as human food.

(b) Any organ or other part of a carcass which is affected by a tumor where there is evidence of metastasis or that the

general condition of the bird has been affected by the size,
position, or nature of the tumor, must be condemned.

Done in Washington, DC.

Paul Kiecker,
Administrator.

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